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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/250,056 | 02/12/1999 | JAMES D. MARKS | 2307E-852 | 1647 |

22798 7590 06/21/2005

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
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EXAMINER

HELMS, LARRY RONALD

| | |
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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/250,056

Applicant(s)

MARKS ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,34-44 and 53-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-5, 11-15, 34-40, 43-44, 53-67 is/are allowed.
- 6) ☒ Claim(s) 6-10,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3-15, 34-44, 53-67 are pending and under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Rejections Withdrawn

3. The rejection of claims 3-5, 11-13, 39-40, and 61-63, under 35 U.S.C. 112, first paragraph, is withdrawn in view of arguments.
4. The rejection of claims 1, 34-38, 53-54 and claims 55-57, 59-60, 67 under 35 U.S.C. 103(a) as being unpatentable over Xu et al (int. J. Cancer 53:401-8, 1993) and further in view of Bird et al (Science 242:423-426, 1988, PTO-892 part of #15) and Chaudhary et al (PNAS 87:1066-70, 1990) is withdrawn in view of the declaration filed 4/7/05.
5. The rejection of claims 1, 34-38, 53-54 and claims 55-57, 59-60, 67 under 35 U.S.C. 103(a) as being unpatentable over Shawver et al (Cancer Res 54:1367-1373, 1994) and further in view of Bird et al (Science 242:423-426, 1988, PTO-892 part of #15) and Chaudhary et al (PNAS 87:1066-70, 1990) is withdrawn in view of the arguments presented in the response of 1/18/05.
6. The rejection of claims 1, 3-13, 39-42, 55, 67 under 35 U.S.C. ' 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments in the claims.

Art Unit: 1642

7. The rejection of claims 1, 34-38, 53-54 and claims 55-60, 62, 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shawver et al (Cancer Res 54:1367-1373, 1994) and further in view of Bird et al (Science 242:423-426, 1988, PTO-892 part of #15) and Chaudhary et al (PNAS 87:1066-70, 1990) and Schier et al (JMB 255:28-43, 1996, IDS) is withdrawn in view of the amendments to the claims.

8. The rejection of claims 1, 34-38, 53-54 and claims 55-60, 62, 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al (int. J. Cancer 53:401-8, 1993) and further in view of Bird et al (Science 242:423-426, 1988, PTO-892 part of #15) and Chaudhary et al (PNAS 87:1066-70, 1990) and Schier et al (JMB 255:28-43, 1996, IDS) is withdrawn in view of the declaration filed 4/7/05.

Response to Arguments

9. The rejection of claims 6-10, 41-42, under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 1/18/05 and 4/7/05 has been carefully considered but is deemed not to be persuasive. The response filed 1/18/05 states that the "open language" in the claims of comprising a CDR or at least two CDRs does not exclude the presence of additional CDRs and "While one skill in the art would probably not prepare antibody sequences having less than the desired number of CDRs..., such antibody derivatives could be readily prepared and screened" (see page 11 of response). In response to this argument, the claims still encompass an antibody with only one or two CDRs and as stated in the response one skill in the art would not want to prepare such antibodies. While one could make n CDR, there is no indication in the specification or in

Art Unit: 1642

the prior art that a single CDR sequence of SEQ ID NO:1 or 2 would bind antigen or have the claimed properties of claim 1. While there are some very specific example of single CDRs of heavy chain CDR3 that do show some binding this is the exception and not the rule. Therefore, one skill in the art would be forced into undue experimentation to screen or even produce an antibody with the claimed properties containing only one or two CDRs. As such the rejection is maintained. Therefore, it would require undue experimentation to produce the claimed invention.

Summary

10. Claims 1-5, 11-15, 34-40, 43-44, 53-67 are in condition for allowance.
11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1642

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER